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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,576	02/09/2001	Olivier Civelli	P-UC 4530	1610

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EXAMINER
LI, RUIXIANG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/780,576	CIVELLI ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08/15/2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet.*

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *3,9,14,19 and 46-53.*

Claim(s) objected to: _____.

Claim(s) rejected: *1,4-7,10-12,15-17,20 and 34-45.*

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): the rejection of claims 1, 4-7, 10-12, 15-17, and 20 under 35 U.S.C. 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: the rejection of claims 1, 4-7, 10-12, 15-17, 20, and 34-45 under 35 U.S.C. 112, 1st paragraph for scope enablement remains.

Applicants argue that the specification teaches binding domains and portions of SEQ ID NO: 2 critical for activity, for example, by disclosing tht modifications of residues within the second intracellular loop and the N and C segments of the third intracellular loop of SEQ ID NO: 2 are predicted to be less well tolerated than modifications to other parts of the receptor (page 10, line 27 to apge 11, line 11); and residues in the transmembrane helices of SEQ ID NO: 2 are predicted to be less well tolerated than modifications to other parts of the receptor (page 10, lines 18-26).

This has been fully considered, but is not deemed to be persuasive because general guidance on modifying amino acid residues of a GPCR, as is the case here, is not sufficient to guide an artisan to make an ADP-glucose receptor polypeptide which is at least 85%, 95%, or 99% identical to SEQ ID NO: 2 while retaining its function. More importantly, the specification fails to disclose the binding domains of the ADP-glucose receptor of SEQ ID NO: 2 and the residues that are critical for its activity, even though the specification asserts that modification of residues within the effector binding regions of SEQ ID NO: 2 are predicted to be less well tolerated than modifications to other parts of the receptor.

Applicants argue that one skilled in the art would have readily made a species ortholog having at least 85% identity with SEQ ID NO: 2, such as those decribed in the art (Exhibits A, B, and C), using routine methods.

This has been fully considered, but is not deemed to be persuasive because none of the amino acid sequences in the Exhibits is a functional ADP-glucose receptor. For example, Exhibit A is a P2Y12 platelet ADP receptor, not an ADP-glucose receptor. Even applicants have not demonstrated that these amino acid sequences have the same functions as that of SEQ ID NO: 2. Thus, it would require undue experimentation to make a functional analogue of the polypeptide of SEQ ID NO: 2 and to use the claimed method.

Applicants argue that a working example is not required and that the specification provides sufficient disclosure to teach those of ordinary skill how to make and use the invention as claimed.

This has been fully considered, but is not deemed to be persuasive because while a working example is not absolutely required to satisfy the enablement requirement under 35 U.S.C. 112, 1st paragraph, it is one of the factors to be considered. In the instant case, since the specification fails to disclose the binding domains of the ADP-glucose receptor of SEQ ID NO: 2 and the residues that are critical for its activity, fails to provide sufficent guidance on how to make functional analogues of SEQ ID NO: 2, and fails to provide working examples, the specification does not enable the claimed method using analogues of SEQ ID NO: 2.

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